MARYLAND HEALTH CARE COMMISSION

HEALTH RESOURCES

STATISTICAL BRIEF

CARDIAC SURGERY AND PERCUTANEOUS CORONARY INTERVENTION SERVICES

This statistical brief is one of a series designed to provide data annually for monitoring the availability and utilization of certain health care resources in compliance with the Commission's State Health Plan for Facilities and Services. Under COMAR 10.24.17, existing providers of cardiac surgery and percutaneous coronary intervention services are to collect and report certain data; review conformance to standards for minimum volumes; and comply with the conditions of an approval, exemption, or waiver issued by the Commission. This brief includes the most recent annual data available from the specified sources.

Cardiac surgery refers to surgery on the heart or major blood vessels of the heart, including both open and closed heart surgery. Percutaneous coronary intervention (PCI) refers to a procedure whereby a catheter is inserted in a blood vessel and guided to the site of the narrowing of a coronary artery to relieve coronary narrowing or stenosis. PCI includes both primary (emergency) and elective procedures.

To plan for cardiac services, MHCC has established four Regional Service Areas. The four Regions are:

Eastern Shore Region: Cecil, Kent, Queen Anne's, Caroline, Talbot, Dorchester, Wicomico, Worcester, and Somerset Counties.

Metropolitan Baltimore Region: Baltimore City and Carroll, Harford, Baltimore, Howard, and Anne Arundel Counties.

Metropolitan Washington Region: Washington, D.C. and Montgomery, Prince George's, Calvert, Charles, and St. Mary's Counties in Maryland.

Western Maryland Region: Garrett, Allegany, Washington, and Frederick Counties.

The Maryland Certificate of Need (CON) Program regulates non-federal hospitals in Maryland; a CON is required for the establishment of a new open heart surgery program. PCI procedures may be performed only in hospitals with on-site cardiac surgical backup, except as provided in the Commission's policies.

For cardiac surgery services, a large number of studies have demonstrated lower mortality rates for hospitals performing higher volumes of procedures. For elective PCI services, studies have also shown a greater incidence of complications and/or death in low volume programs as compared with high volume programs. The volume-outcome relationship has also been demonstrated in the limited data now available for primary PCI.

Based on this evidence, the Commission has established minimum volume requirements for cardiac services. There should be a minimum of 200 open heart surgery procedures performed annually in any institution in which open heart surgery is performed for adult patients.

Effective in 1997, a CON issued by the Commission for a new cardiac surgery program will require as a condition of issuance that the program achieve minimum volume standards within 24 months of beginning operation and maintain a level of utilization at or above the minimum volume in each subsequent year of operation.

Over the past decade, initiatives designed to support improvements in the quality of cardiac services have emphasized measurement and reporting of outcomes (such as in-hospital mortality) as well as improving the processes of care (for example, increasing adherence to clinical practice guidelines). In early 2002, the Commission established the Advisory Committee on Outcome Assessment in Cardiovascular Care to recommend strategies for developing an ongoing, statewide program to improve the quality of cardiovascular care in Maryland. In March 2004, the Commission updated the State Health Plan (SHP) to reflect the findings and recommendations of the Advisory Committee on interventional cardiology services.

CARDIAC SURGERY

Open heart surgery (OHS) means cardiac surgery during which a heart-lung machine (i.e., cardiopulmonary bypass or CPB) may temporarily assume the functions of the patient's heart and lungs. Minimally invasive procedures that do not require the use of CPB support, called off-pump bypass or "beating heart" surgery, are also included.

There are currently nine Maryland hospitals performing cardiac surgery and elective PCI services. In addition, there are currently three Washington, D.C. hospitals that the Commission considers in its Metropolitan Washington planning region for cardiac surgery. (Georgetown University Hospital consolidated its program with Washington Hospital Center on August 1, 2003.)

In 2003, three hospitals in the Metropolitan Washington Region performed fewer than the minimum volume of 200 open heart surgery procedures. All hospitals in the other Regional Service Areas exceeded the minimum volume of procedures.

Adult Open Heart Surgery Procedures: Maryland and Washington, D.C. Hospitals, 2001-2003.

Region/Facility	2001	2002	2003
Western Maryland Region			
Sacred Heart Hospital	242	285	389
Metropolitan Washington Region			
Prince George's Hospital Center	150	159	155
Washington Adventist Hospital	770	739	721
Total Maryland	*920*	*898*	*876*
Georgetown University Hospital*	269	260	92
George Washington Univ Hospital	177	190	261
Howard University Hospital	20	23	16
Washington Hospital Center	2,324	2,252	2,152
Total Washington, D.C.	*2,790*	*2,725*	*2,521*
Metropolitan Washington Total	***3,710***	***3,623***	***3,397***
Metropolitan Baltimore Region			
St Joseph Medical Center	1,226	1,181	1,075
Johns Hopkins Hospital	1,063	946	853
Sinai Hospital	544	522	521
Union Memorial Hospital	1,074	938	815
University of Maryland Med Ctr	427	490	435
Metropolitan Baltimore Total	***4,334***	***4,077***	***3,699***
Eastern Shore Region			
Peninsula Regional Med Ctr	650	673	592
Total	**8,936**	**8,658**	**8,077**

Adult cases were identified as 15 years of age or older.
Source: Maryland Hospital Discharge Abstracts, 2001 (file created 6/3/2003), 2002 (file created 9/25/2003), 2003 (file created 6/14/2004). DC Hospital Discharge Abstracts, 2001, 2002, 2003.
* Georgetown University Hospital consolidated its OHS program with WHC on August 1, 2003.

Coronary artery bypass graft (CABG) surgery is one of the most frequent major surgical procedures performed in the United States; however, national data show that the number of procedures began to decline in 1998.[1] From 2001 to 2003, regional volumes declined in all areas except Western Maryland.

With an aim of minimizing mortality and morbidity surgeons have progressed towards less invasive procedures. Cardiopulmonary bypass adversely affects many organ systems, and the potential benefits of off-pump coronary artery bypass (OPCAB) surgery are significant. CPB has been associated with a one percent to five percent incidence of stroke and other complications including postoperative low cardiac output syndrome, adult respiratory distress syndrome, bleeding, and renal insufficiency. Several retrospective studies have suggested that OPCAB may reduce morbidity and/or mortality. Nearly all reports have demonstrated reductions in the need for transfusion of blood products, shorter stays in the intensive care unit, and shorter postoperative lengths of stay. Some of these studies have also suggested that hospital costs are reduced.[2]

According to recent data from the Society for Thoracic Surgeons database, OPCAB accounts for just 23 percent of all isolated bypass procedures performed in the United States (Peterson ED, unpublished Society of Thoracic Surgeons data, 2003).[3]

In Maryland hospitals, the range of OPCAB surgery performed in 2003 ranged from 3 percent to 67 percent. The hospitals located in Washington, D.C. reported a greater percentage of procedures as off-pump, 61 percent overall. In the two-year period from 2002 to 2003, the total number of OPCAB procedures increased nearly 12 percent, and the percentage of CABG procedures performed as OPCAB increased about 7 percent. In 2003, 38 of the 2,660 OPCAB procedures were CABG procedures with aortic or mitral valve replacement or mitral valve repair.

Percentage of Adult Coronary Artery Bypass Graft Procedures Performed Off-Pump: 2002-2003.

	2002		2003	
Region/Facility	All CABG	Off-Pump %	All CABG	Off-Pump %
Western Maryland Region				
Sacred Heart Hospital	266	1.5	369	33.3
Metropolitan Washington Region				
Prince George's Hospital Center	136	22.8	138	26.1
Washington Adventist Hospital	634	24.9	629	25.0
Total Maryland	*770*	*24.5*	*767*	*24.9*
Georgetown University Hospital*	217	46.5	67	65.7
George Washington Univ Hospital	156	11.5	207	81.6
Howard University Hospital	22	9.1	12	83.3
Washington Hospital Center	1,979	45.6	1,858	58.0
Total Washington, D.C.	*2,374*	*43.1*	*2,144*	*60.6*
Metropolitan Washington Total	***3,144***	***38.6***	***2,911***	***51.3***
Metropolitan Baltimore Region				
St Joseph Medical Center	1,034	23.0	947	19.6
Johns Hopkins Hospital	677	13.6	526	11.2
Sinai Hospital	447	3.1	382	2.9
Union Memorial Hospital	857	69.5	766	66.8
Univ of Maryland Med Ctr	405	40.5	410	55.9
Metropolitan Baltimore Total	***3,420***	***32.3***	***3,031***	***32.9***
Eastern Shore Region				
Peninsula Regional Med Ctr	581	9.8	506	9.3
Total	**7,411**	**32.1**	**6,817**	**39.0**

Source: Maryland Hospital Discharge Abstracts, 2002 (file created 9/25/2003), and 2003 (file created 6/14/2004). DC Hospital Discharge Abstracts, 2002 and 2003.
CABG - Any procedure, principal or other, with an ICD-9-CM code of 36.10, 36.11, 36.12, 36.13, 36.14, 36.15, 36.16, 36.17, or 36.19. CABG procedures with cardiopulmonary bypass were identified as any of the above ICD-9-CM procedure codes, with an ICD-9-CM code of 39.61, that is, the use of a heart and/or lung bypass machine. The remaining records were taken to be off-pump procedures.
* Georgetown University Hospital consolidated its OHS program with WHC on August 1, 2003.

PERCUTANEOUS CORONARY INTERVENTION

Improvements in the technique of percutaneous coronary intervention coupled with expanded indications have increased the number of patients receiving this therapy over the past decade. There are generally two types of PCI procedures. While the large majority of PCI procedures are performed as elective procedures, PCI is also used as a primary means of revascularization in the emergency

[1] Available at: http://www.cdc.gov/nchs/about/major/hdasd/listpubs.htm and http://www.ctsnet.org/file/STSNationalDatabaseSpring2004AdultCardiacExecutiveSummary.pdf

[2] Eagle KA, Guyton RA, Davidoff R, Edwards FH, Ewy GA, Gardner TJ, Hart JC, Herrmann HC, Hillis LD, Hutter AM Jr, Lytle BW, Marlow RA, Nugent WC, Orszulak TA. ACC/AHA 2004 guideline update for coronary artery bypass graft surgery: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Update the 1999 Guidelines for Coronary Artery Bypass Graft Surgery). American College of Cardiology Web Site. Available at: http://www.acc.org/clinical/guidelines/cabg/index.pdf, page 56.

[3] Peterson ED and Mark DB. Off-pump bypass surgery -- Ready for the big dance? *JAMA* 2004 Apr 21; 291:1897-9.

treatment of certain patients with acute ST-segment elevation myocardial infarction (MI).

When PCI is used to treat certain acute MI patients, rather than thrombolytic therapy (the use of drugs to dissolve or break up blood clots), the procedure is referred to as primary PCI. Primary PCI procedures comprise a relatively small number in comparison to elective procedures. (In the discharge abstracts, primary angioplasty is not specifically identifiable in the procedural coding.)

Adult PCI Procedures: Maryland and Washington, D.C. Cardiac Surgery Hospitals, 2001-2003.

Region/Facility	2001	2002	2003
Western Maryland Region			
Sacred Heart Hospital	211	420	565
Metropolitan Washington Region			
Prince George's Hospital Center	466	460	469
Washington Adventist Hospital	1,685	1,908	2,242
Total Maryland	*2,151*	*2,368*	*2,711*
Georgetown University Hospital*	296	297	127
George Washington Univ Hospital	321	453	457
Howard University Hospital	49	72	61
Washington Hospital Center	3,645	3,421	4,024
Total Washington, D.C.	*4,311*	*4,243*	*4,669*
Metropolitan Washington Total	***6,462***	***6,611***	***7,380***
Metropolitan Baltimore Region			
St Joseph Medical Center	2,234	2,581	2,775
Johns Hopkins Hospital	1,400	1,278	1,254
Sinai Hospital	1,147	1,222	1,174
Union Memorial Hospital	1,550	1,731	1,879
University of Maryland Med Ctr	503	416	581
Metropolitan Baltimore Total	***6,834***	***7,228***	***7,663***
Eastern Shore Region			
Peninsula Regional Med Ctr	1,498	1,484	1,513
Total	**15,005**	**15,743**	**17,121**

PCI procedures were identified as any procedure, principal or other, with an ICD-9-CM code of 36.01, 36.02, or 36.05.
Source: Maryland Hospital Discharge Abstracts, 2001 (file created 6/3/2003), 2002 (file created 9/25/2003), 2003 (file created 6/14/2004). DC Hospital Discharge Abstracts, 2001, 2002, 2003.
* Georgetown University Hospital consolidated its OHS program with WHC on August 1, 2003.

In 2003, two hospitals in the Metropolitan Washington Region performed fewer than the recommended minimum institutional volume of 200 PCI procedures annually at centers with on-site cardiac surgery.[4]

The total number of PCI procedures at cardiac surgery hospitals in Maryland and Washington, D.C. increased by 2,116 (14 percent) from 2001 to 2003. Over the same three-year period, the number of open heart surgery procedures decreased by 859 (nearly 10 percent).

In April 2003, the U.S. Food and Drug Administration (FDA) approved the first drug-eluting stent (DES) for PCI procedures; a second DES received FDA approval in March 2004. PCI cases using DESs accounted for more than half of all PCI procedures performed at cardiac surgery hospitals from July through December 2003. The stents are coated with medication that is gradually released into the wall of the coronary artery to suppress scar tissue formation inside the artery (restenosis or re-narrowing). Previously, the long-term benefits of PCI were limited by the occurrence of restenosis (15-30 percent); however, DESs have been shown to dramatically reduce the rates of restenosis to five percent or less.

Adult PCI Procedures Using DES: Maryland and Washington, D.C. Cardiac Surgery Hospitals, July-December 2003.

Region/Facility	All PCI	PCI Cases using Drug-Eluting Stents: Number	PCI Cases using Drug-Eluting Stents: %
Western Maryland Region			
Sacred Heart Hospital	309	142	46.0
Metropolitan Washington Region			
Prince George's Hospital Center	227	88	38.8
Washington Adventist Hospital	1,083	751	69.3
Total Maryland	*1,310*	*839*	*64.0*
Georgetown University Hospital*	5	3	60.0
George Washington Univ Hospital	225	138	61.3
Howard University Hospital	24	4	16.7
Washington Hospital Center	2,127	1,273	59.8
Total Washington, D.C.	*2,381*	*1,418*	*59.6*
Metropolitan Washington Total	***3,691***	***2,257***	***61.1***
Metropolitan Baltimore Region			
St Joseph Medical Center	1,427	874	61.2
Johns Hopkins Hospital	623	450	72.2
Sinai Hospital	587	164	27.9
Union Memorial Hospital	932	324	34.8
University of Maryland Med Ctr	291	151	51.9
Metropolitan Baltimore Total	***3,860***	***1,963***	***50.9***
Eastern Shore Region			
Peninsula Regional Med Ctr	785	310	39.5
Total	**8,645**	**4,672**	**54.0**

PCI procedures were identified as any procedure, principal or other, with an ICD-9-CM code of 36.01, 36.02, or 36.05; procedures using a DES were identified as any PCI procedure (as above) with an ICD-9-CM code of 36.07, that is, insertion of drug-eluting coronary artery stent(s).
Source: Maryland Hospital Discharge Abstracts, 2003 (file created 6/14/2004). DC Hospital Discharge Abstracts, 2003.
* Georgetown University Hospital consolidated its OHS program with WHC on August 1, 2003.

An analysis by the Advisory Board's Cardiovascular Roundtable estimates a reduction in CABG volumes of between 20 and 29 percent across a five-year timeframe. Using detailed procedural data from a cardiac program that was among the nation's top 20 providers in terms of procedural volumes and was a participant in a DES trial, the Roundtable analyzed discharges from May 2001 through April 2002. The PCI cases were representative of those in national registries; however, the use of stents exceeded national practice. The analysis used several criteria to segment cases, including ACC/AHA guidelines for CABG surgery.[5] The literature also includes retrospective reviews of coronary angiograms and medical records at two tertiary centers that estimated reductions of 17 percent[6] and 21

[4] Smith SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *JACC*, Vol. 37, No. 8, June 15, 2001:1-66.

[5] The Advisory Board Company, Cardiovascular Roundtable. Enterprise in Transition, Volume 1: Drug-Eluting Stents – Assessing the impact on program volumes, profits, and future prospects. 2003.

[6] Powell BD, Rihal CS, Bell MR, Zehr KJ, Holmes DR Jr. Anticipated impact of drug-eluting stents on referral patterns for coronary artery bypass graft surgery: a population-based angiographic analysis. *Mayo Clin Proc*. 2004 Jun;79(6):769-772.

percent[7] in the cardiac surgical volumes at the institutions as a consequence of drug-eluting stents. The long-term effects of DESs on interventional cardiology and cardiovascular surgery services may not be known for two or three years.

The introduction of DESs in the United States has not been without complications. Post-approval reporting requirements were a condition of FDA approval. Less than two months after its approval of the first DES, the FDA issued a warning to physicians, in the use of Cordis' CYPHER stents, in regard to thrombosis. Further concerns were raised about the use of incorrect stent size for the length of the occluded arterial area. Correct stent sizing is crucial in proper stent placement, and incorrect use can lead to complications, specifically thrombosis or re-occlusion. It was also found that recommendations to administer anti-clotting medications for three months instead of the usual two weeks were not being followed. The FDA has advised physicians to use the stents according to the labeling, particularly with regard to patient selection and appropriate peri-procedural medications.[8]

Also, within months of FDA approval, Boston Scientific had to recall over 88,000 Taxus stents, during the period of July to August 2004, due to a non-deflation problem. Patients who already had the Taxus stent in place were not at risk. The FDA is working on guidelines for manufacturers.[9]

PCI Waivers

State health planning policy requires that PCI procedures be performed only in hospitals with on-site cardiac surgical backup; however, the Commission may waive its policy if the exemption meets specific conditions.

The current SHP (effective March 15, 2004), as recommended by the Interventional Cardiology Subcommittee of the Advisory Committee on Outcome Assessment in Cardiovascular Care, allows for the Commission to establish a process that permits hospitals without on-site cardiac surgery, upon demonstrating the ability to comply with applicable requirements for primary PCI programs, to obtain a waiver to provide primary PCI services. The waivers will be issued for a two-year period. The Commission, upon request by the hospital, may renew a primary PCI waiver provided that the hospital has met and will continue to meet all requirements for primary PCI programs without on-site cardiac surgery. A hospital receiving a primary PCI waiver is required to collect and report complete and accurate demographic, clinical, process, and outcome data for primary PCI patients.

C-PORT Hospitals

In 1996, the Maryland Health Resources Planning Commission, a predecessor agency of the Maryland Health Care Commission, approved a waiver from the requirement for on-site cardiac surgical backup, for the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) project, to permit a small number of Maryland hospitals to participate in a research study to evaluate the safety and efficacy of providing primary PCI in hospitals without on-site cardiac surgery versus thrombolytic therapy for the treatment of acute myocardial infarction.

Originally granted on January 15, 1996, the exemption was extended on a number of occasions, most recently in June 2003, permitting the Commission to act on an updated State Health Plan reflecting the findings and recommendations of the Advisory Committee on Outcome Assessment in Cardiovascular Care.

From 1996 to 1999, the C-PORT project enrolled patients in a randomized, clinical trial. Although only 18 percent of the planned sample size was actually enrolled in the trial, the data from this study made an important contribution to the knowledge base concerning whether primary angioplasty services can be provided safely by hospitals without on-site cardiac surgery programs.[10] In its second phase, which began in August 1999, the C-PORT project is functioning as a registry.

Maryland hospitals currently participating in the C-PORT registry are Suburban Hospital, Johns Hopkins Bayview Medical Center, Shady Grove Adventist Hospital, St. Agnes Hospital, Holy Cross Hospital, Memorial Hospital at Easton, North Arundel Hospital, Southern Maryland Hospital Center, Anne Arundel Medical Center, Franklin Square Hospital Center, Howard County General Hospital, and Doctor's Community Hospital. The hospitals will continue to submit data to the C-PORT registry until the primary PCI waiver process is established.

[7] Ferreira AC, Peter AA, Salerno TA, Bolooki H, de Marchena E. Clinical impact of drug-eluting stents in changing referral practices for coronary surgical revascularization in a tertiary care center. *Ann Thorac Surg*. 2003 Feb;75(2):485-489.
[8] FDA Public Health Web Notification, issued 10/18/2004. Available at: http://www.fda.gov/cdrh/safety/cypher3.html.
[9] R. Kerber, Drug-coated stents may face additional FDA scrutiny. *Boston Globe*, May 3, 2004.
[10] Aversano T, Aversano LT, Passamani E, Knatterud GL, Terrin ML, Williams DO, Forman SA; Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT). Thrombolytic therapy vs primary percutaneous coronary intervention for myocardial infarction in patients presenting to hospitals without on-site cardiac surgery: a randomized controlled trial. *JAMA*. Vol. 287, No. 15. Apr 17, 2002: 1943-1951.